

REMARKS

The present application was filed on September 27, 2001 having claims 1-29. Claims 16-29 have been withdrawn from consideration. Claims 1-15 remain pending in the application.

In the Office Action dated October 1, 2003, the Examiner: (1) objected to the disclosure because of the use of trademarks "Syl-Off" and "Medical Fluid" without capitalization and accompaniment with generic terminology; (2) rejected claims 1, 2, 5-7 and 9-14 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,911,711 to Pelkey; and (3) rejected claims 3-4, 8 and 15 under 35 U.S.C. §103(a) as obvious over Pelkey in view of U.S. Patent No. 5,456,948 to Mathisen et al.

With respect to the objection to the specification, applicants have amended those sections which recited Syl-Off and Medical Fluid; thus, the objection is believed to have been overcome.

Claims 1, 2, 5-7 and 9-14 were rejected under 35 U.S.C. §103(a) as obvious over Pelkey. According to the Examiner, "Pelkey teaches a method of coating a needle, which inherently has a surface, by applying a coating mixture to the surface of the needle. The coating mixture of Pelkey contains a polydialkylsiloxane, with a viscosity of 12,500 . . . and one other siliconization material . . . known by MDX4-4159. The mixture of Pelkey is then cured . . . as required by claim 1." (October 1, 2003 Office Action at page 4.)

However, the Examiner fails to note that Pelkey's materials are applied in multiple coatings. Nowhere does Pelkey disclose applying a coating mixture comprising at least one polydialkylsiloxane having a molecular weight sufficient to provide a viscosity of the coating mixture of at least about 10,000 cp and at least one other siliconization material and curing the coating mixture. To the contrary, Pelkey discloses that its

Lubricious coating 24 has a first layer 26 formed from an at least partially cured organosiloxane copolymer and polydimethylsiloxane The lubricious coating has a second layer 28, applied as a secondary operation onto first layer 26, that includes a polydimethylsiloxane having a viscosity between about 50 centistokes and about 350 centistokes.

Pelkey, in fact, is completely silent with respect to the viscosity the combined materials in the first layer of its coating. While Pelkey states that its first layer includes a polydimethylsiloxane having a “viscosity greater than about 1000 centistokes (col. 3, lines 41-43),” preferably about 12,500 centistokes, nowhere does Pelkey describe the actual viscosity of the first layer of the coating, and nowhere is there any suggestion the viscosity of the mixture of materials making up Pelkey’s first layer is at least about 10,000 cp as required by applicants’ claim 1. While the Examiner asserts Pelkey’s coatings would inherently possess Applicants’ claimed viscosity, nowhere is there any suggestion of such a viscosity.

Moreover, nowhere does Pelkey disclose or suggest that its coating mixture may be utilized for surgical needles. In fact, as admitted by the Examiner, Pelkey’s coating method is directed to hypodermic needles. (See Office Action at page 5.) As one skilled in the art would readily appreciate, there is a difference between the use of a hypodermic needle, which is used either a single time or a very few times (e.g., for the administration of a local anesthetic) and thus has limited penetration in a patient, and the use of a surgical needle, which may be passed through a patient’s tissue numerous times to adequately close a wound.

With respect to claims 10-13, the Examiner takes the position that it would have been obvious to store Pelkey’s needles under ambient conditions, which could encompass the temperature and humidity ranges of claims 10-13. However, in order to establish the *prima facie* obviousness of a claim, “there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.” See MPEP §2143.

This Pelkey fails to accomplish. Nowhere in Pelkey is there any teaching or suggestion to cure the compositions on its needles by “subjecting the coating mixture to an atmosphere of from about 20% to about 80% relative humidity, at a temperature from about 10° C. to about 50° C. for a time period ranging from about 1 hour to about 6 hours; and, heating the coating mixture to a temperature of from about 100° C. to about 200° C. for a time period ranging from about 2 hours to about 48 hours” as required by

claims 10 and 11. Similarly, there is no teaching or suggestion in Pelkey to cure the compositions on its needles by "subjecting the coating mixture to an atmosphere of from about 50% to about 65% relative humidity, at a temperature from about 20° C. to about 35° C. for a time period ranging from about 2 hours to about 4 hours; and, heating the coating mixture to a temperature of from about 115° C. to about 150° C. for a time period ranging from about 15 hours to about 25 hours" as required by claims 12 and 13.

While the Examiner suggests one skilled in the art would have known the temperature and time to cure these materials, there is no support for this assertion. Nor is there any teaching or suggestion in Pelkey for the parameters found in Applicants' multiple stage curing process. Should the Examiner maintain this rejection, it is respectfully requested that the Examiner identify where, in fact, this multi-step curing process to obtain a viscosity of at least about 10,000 cp as claimed by Applicants is, in fact, known.

The Examiner has next rejected claims 3-4, 8 and 15 under 35 U.S.C. §103(a) as obvious over Pelkey in view of Mathisen et al. Mathisen et al. fails to remedy the deficiencies of Pelkey. According to the Examiner, Mathisen discloses a method of lubricating medical articles, including surgical needles, with a solution of polydialkylsiloxane in hexane, properly considered a nonpolar solvent. However, nowhere is there any teaching or suggestion in Mathisen of applying a coating mixture on the surface of the needle, the coating mixture comprising at least one polydialkylsiloxane having a molecular weight sufficient to provide a viscosity of the coating mixture of at least about 10,000 cp and at least one other siliconization material; and, curing the coating mixture on the surface of the needle to provide a silicone coating thereon as required by applicants' claim 1. As Claim 1 is non-obvious for the reasons described above, claims 3-4, 8 and 15 incorporate all of the limitations of their dependent base claim and thus are also non-obvious over Pelkey and Mathisen et al. no matter how the references are combined.

It is believed that the claims of the application as now presented, i.e., claims 1-15, are patentably distinct over the art of record and are in condition for allowance. In the event that the examiner believes that a telephone conference or a personal interview may

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facilitate resolution of any remaining matters, the undersigned may be contacted at the number indicated below. In view of the foregoing amendment and remarks, early and favorable reconsideration of this application is respectfully requested.

Respectfully submitted,



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